

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-27, drawn to a binding agent.

Group II, claim(s) 30-33, drawn to a method of making a binding agent.

Group III, claim(s) 34, drawn to composition.

Group IV, claim(s) 35, drawn to a method of causing aggregation of a plurality of binding agents.

Group V, claim(s) 36, drawn to a kit.

Group VI, claim(s) 37-46, drawn to a method of determining an analyte in a sample.

Group VII, claim(s) 47, drawn to a method of determining an analyte in a sample.

Group VIII, claim(s) 48, drawn to a method of determining an analyte in a sample.

Group IX, claim(s) 49, drawn to a method of determining an analyte in a sample.

Group X, claim(s) 50-58, drawn to a method of causing an aggregation of a therapeutic agent at a physiological site.

Group XI, claim(s) 59-60, drawn to a method of causing aggregation of a therapeutic agent in a culture of cells.

NOTE: It is noted that claim 22 depends from itself. However, the Examiner has placed claim 22 with Group I, as it appears that it should belong with Group I. Also, claim 56 does not recite which claim it depends from. However, claims 56-57 have been placed with Group X, as it appears that these claims would belong with Group X.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The technical feature linking Groups I-XI appears to be the binding agent.

However, Taylor (US 20020168645) disclose a binding agent comprising two binding moieties a binding member such as biotin which has been reversibly masked and the binding partner such as streptavidin (e.g. para 0148). Taylor discloses that when the biotin is demasked that the biotin binds to the streptavidin (e.g. 0148).

Therefore, the technical feature linking the inventions of Groups I-XI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Applicant is advised that a reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

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All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/Melanie Yu/
Primary Examiner, Art Unit 1641